

**Notice of Allowability**

Application No.

09/927,773

Applicant(s)

POTTS ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/23/04.
2. ☒ The allowed claim(s) is/are 1-7 and 10-36.
3. ☒ The drawings filed on 10 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20040914.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/04 has been entered.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara McClung on 9/14/04.

The application has been amended as follows:

In the claims:

Claims 5, 23, and 32 : Delete "at said further time interval" in line 3 of each claim.

Replace claim 15 with the following:

A glucose monitoring system for measuring glucose in a subject, said system comprising, in operative combination:

a sensing mechanism in operative contact with the subject or with a glucose-containing sample extracted from the subject, wherein said sensing mechanism obtains a raw signal specifically related to glucose amount or concentration in the subject;

a first device to obtain skin conductance readings or temperature readings from the subject; and

one or more microprocessors in operative communication with the sensing mechanism, wherein said microprocessors comprise programming to

(i) control the sensing mechanism to obtain a series of raw signals at selected time intervals,

(ii) correlate the raw signals with glucose measurement values indicative of the amount or concentration of glucose present in the subject to obtain a series of glucose measurement values,

(iii) predict a glucose measurement value at a further time interval, subsequent to obtaining the series of measurement values,

(iv) compare said predicted glucose measurement value to a threshold glucose value, wherein a predicted glucose measurement value less than or equal to the threshold glucose value is designated to be hypoglycemic,

(v) control the first device to measure skin conductance readings or temperature readings of the subject,

(vi) compare said skin conductance readings or temperature readings with a threshold skin conductance or temperature value or trend of skin conductance or temperature values to determine whether said skin conductance readings or temperature readings indicate a hypoglycemic event, and

(vii) predict a hypoglycemic event in said subject when both (a) comparing said predicted glucose measurement value to said threshold glucose value indicates a hypoglycemic event at said further time interval, and (b) comparing said skin conductance readings or temperature readings with a threshold skin conductance or temperature value or trend of skin conductance or temperature values indicates a hypoglycemic event.

Claim 24: in line 2, replace "a" with --the-- before "glucose".

Replace claim 26 with the following:

One or more microprocessors comprising programming to:

(i) control a sensing mechanism to obtain a series of raw signals at selected time intervals, wherein the raw signals are related to an amount or concentration of glucose in a subject,

(ii) correlate the raw signals with glucose measurement values indicative of the amount or concentration of glucose present in the subject to obtain a series of glucose measurement values,

(iii) predict a glucose measurement value at a further time interval, subsequent to obtaining the series of measurement values,

(iv) compare said predicted glucose measurement value to a threshold glucose value, wherein a predicted glucose measurement value less than or equal to the threshold glucose value is designated to be hypoglycemic,

(v) control a first device to measure skin conductance readings or temperature readings of the subject,

(vi) compare said skin conductance readings or temperature readings with a threshold skin conductance or temperature value or trend of skin conductance or temperature values to determine whether said skin conductance readings or temperature readings indicate a hypoglycemic event, and

(vii) predict a hypoglycemic event in said subject when both (a) comparing said predicted glucose measurement value to said threshold glucose value indicates a hypoglycemic event at said further time interval, and (b) comparing said skin conductance readings or temperature readings with a threshold skin conductance or temperature value or trend of skin conductance or temperature values indicates a hypoglycemic event.

Claim 30: In line 2, insert --glucose measurement-- after "discrete".

Claim 33: In line 2, replace "a" with --of the-- before "glucose".

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: The arguments set forth in the response of 7/23/04 are persuasive.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 1-7, 10-36 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
9/15/04